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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Eric Berreklouw

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EXAMINER

BUI, VY Q

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

12/21/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,363	Applicant(s) BERREKLOUW, ERIC	
	Examiner VY BUI	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-28,31-37 and 41-55 is/are pending in the application.
- 5a) Of the above claim(s) 1-28 and 41-43 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 31-37,44-53 and 55 is/are rejected.
- 8) ☒ Claim(s) 54 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/11/2010; 3/7/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of a heart valve prosthesis (original claims 31-37) in the reply filed on 10/18/2011 is acknowledged.

New claims 41-43 are withdrawn from further examination as the claims are not drawn to the elected heart valve prosthesis.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation "**the carrier comprises a ring**" in **claims 50-52**, and the limitation "**a constriction ring element**" in **claim 34** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 31, 32, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term **“first penetrated position”** in claim 31 appears to mean “the pins 132/133 have been fully penetrated into the valve annulus tissue in a condition as shown in F 16C”, while the term **“first penetrated position”** in claims 32 and 36 appears to mean “the pins 132/133 are held in an axial condition by sleeve 74/77 (not shown in a figure)”. The term is indefinite because the specification does not clearly define the term.

2. Claims 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation “a ring” in the claims appears to be a double inclusion of “the ring member” in claim 1. Clarification is required.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 31-37, 44-52, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Gabbay-7,311,730 B2.

As to claims 31-37, 44-52, 55, Gabbay discloses a heart prosthesis 10/50/100/250/300 (F 1-8) comprising 1st penetrated position shown in F 5, 2nd penetrated position shown in F 7, pins 18&20 (F 1-2), or pins 110&112 (F 3), or pins 254&264 of temperature activated shape memory alloy (F 4-7; C 3, L 28-45) each defining an arc greater than 180°, ring member 252 (F 5; see also ring member 16 in F 1-2), a carrier/radial arm defined by an 180° arc of each of the pins 18 & 20, pins 110&112, or pins 254&264, constriction ring element 258 (F 5), valve leaflets 140 (F 3) substantially as recited in the claims.

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Please notice the below:

As to claims 33, 35, 37, the carrier/radial arm of a pin is shortened in an axial direction when the pin is moving in a radial inward direction.

As to claims 47-49, the shape memory alloy carrier/radial arm of a pin can be shortened in a radial inward direction when the carrier/radial arm is moving in an axial direction.

As to claims 50-52, the shape memory alloy carrier/ring 252 (F 4) is capable of being compressed to a reduced diameter when the carrier/ring 252 (F 1, 4) is compressed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay-7,311,730 B2 in view of Seiler et al.-US2009/0216115 A1.

As to claim 53, Gabbay-'730 discloses substantially the claimed invention, except for the ring member/pins 18&20, or 110&112 having a material enhancing in-growth of tissue. However, Seiler-'115 (section [0078] and claim 22) discloses an anchor having a drug to enhance tissue growth and anchoring capacity as well. It would have been obvious to one of ordinary skill in the art to provide a tissue enhancing drug/material to ring member/pins 18&20, or 110&112 for enhancing the anchoring capacity of the ring member/pins 18&20 or 110&112 as taught by Seiler-'115.

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Allowable Subject Matter

Claim 54 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EXAMINER whose telephone number is (571)272-4692 and email address is "vy.bui@uspto.gov". The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/
Primary Examiner, Art Unit 3773